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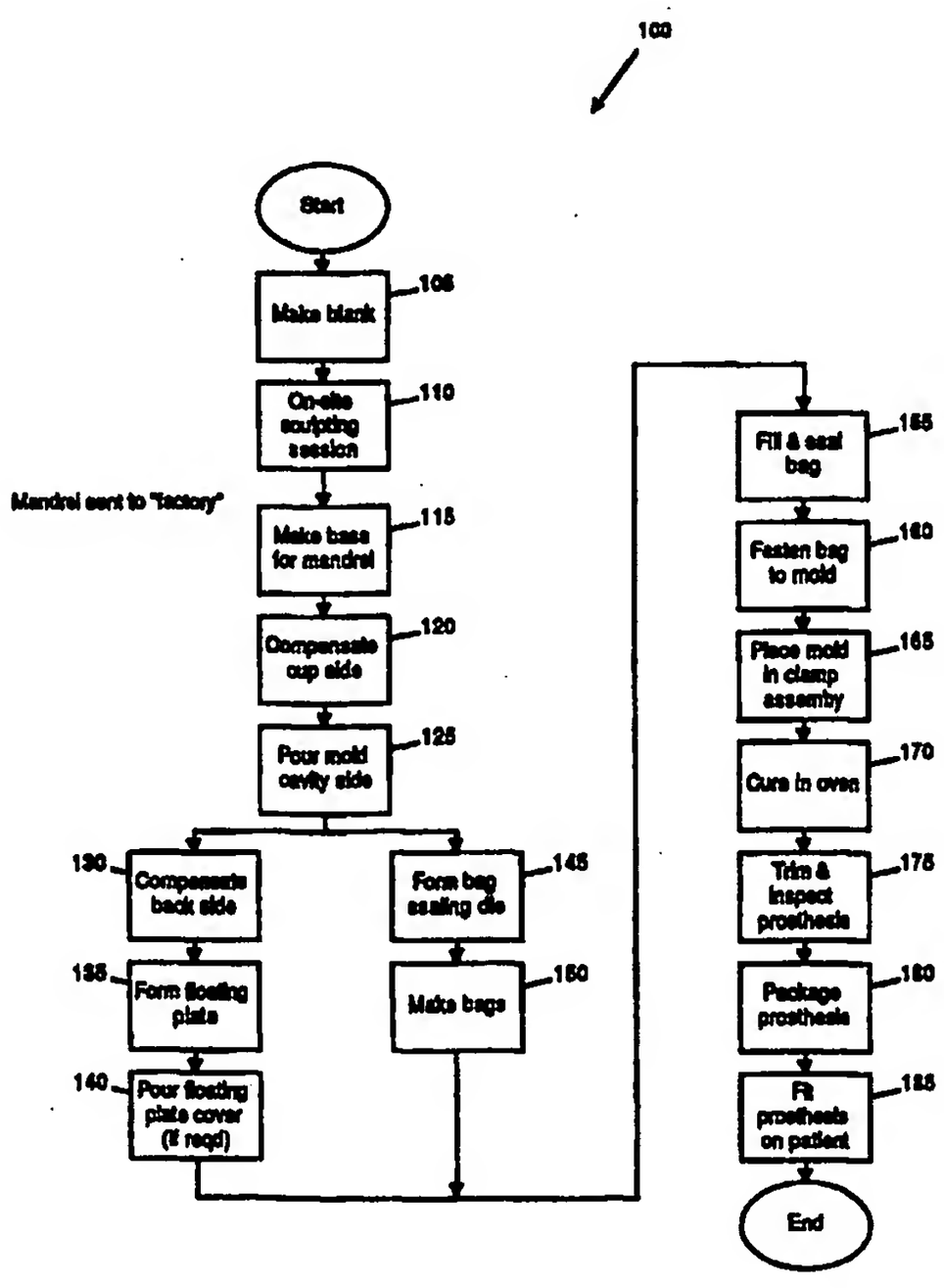
(54) Title: DESIGNING AND MANUFACTURING A CUSTOM BREAST PROSTHESIS

(57) Abstract

The present invention is directed to custom–fitted breast prostheses, and more particularly relates to systems and methods for disigning and manufacturing custom–fitted breast prostheses. One method (100) involves the creation of a visual mandrel using three–dimensional scanning equipment and computer aided design software. The visual mandrel may be stored in a computer and later reused and/or modified as needed by a custom breast prosthesis wearer. A further method involves the creation of a physical mandrel by an interactive sculpting process (110), wherein a patient and a designer develop the shape of the physical mandrel through the exchange of information including comfort, feel, and fit of the mandrel, as well as prior prostheses.



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DESIGNING AND MANUFACTURING A CUSTOM BREAST PROSTHESIS

FIELD OF THE INVENTION

This invention relates in general to external breast prostheses, and more particularly relates to systems and methods for designing and manufacturing custom-fitted breast prostheses.

BACKGROUND OF THE INVENTION

It is an unfortunate fact that many women are diagnosed with breast cancer and must have the affected breast removed. After removal of one or both of her breasts, most mastectomy patients in today's society seek a prosthetic replacement to feel whole, and present a normal appearance beneath clothing. Another goal of breast prostheses is to maintain the balance of the body and to assist in reducing stress on the spine. Early fabric prostheses were never satisfactory, and surgically implanted prostheses are expensive and involve health risks. Therefore, external silicone breast prostheses have become extremely popular with mastectomy patients.

Mastectomy patients may choose from a variety of "off the shelf" external silicone prostheses. Each of the different types of prostheses employ various features in an attempt to provide an acceptable level of comfort and to duplicate the form, feel, weight distribution, fullness, and softness of the natural breast.

The first external silicone breast prostheses included a single volume of a two-component cross-linked silicone material contained within a cavity formed by two pieces of polyurethane film. The silicone material is cured in a mold that determines the shape of the prosthesis. Such prostheses were designed to be worn inside a brassiere. An example of such a prosthesis and a mold are described in U.S. Patent Nos. 4,172,298 and 4,247,351 to Rechenberg.

Later, prosthesis designers determined that certain advantages could be obtained by forming a prosthesis of two volumes of silicone rubber materials having different softness. Such prostheses include three pieces of polyurethane film, which are welded together along a common peripheral edge to form front and rear chambers. In some products, the firmer silicone is in the front chamber. In others, the firmer silicone is in the rear chamber.

U.S. Patent No. 4,950,291 to Mulligan describes a two-chamber prosthesis in which the front chamber is relatively thin. The silicone rubber in the larger rear chamber, which is placed next to the chest wall, is softer than that in the front chamber. The softer silicone conforms to the shape of the chest wall and moves with the body, thereby providing a natural appearance. The softer silicone helps redistribute the weight of the prosthesis across and against the chest wall and away from the brassiere shoulder strap, which reduces stress on the shoulder. The firmer silicone in the front chamber supports the soft rear chamber, prevents the prosthesis from collapsing, and gives shape to the product.

As mentioned above, other two-chamber prostheses place the firmer silicone in the rear chamber. An example of a two-chamber prosthesis of this type is sold by the assignee of the present invention under the trademark "DELTA PERSONALLY." In this prosthesis, the rear chamber, which contains the firmer silicone, is relatively thin. The larger front chamber contains the softer silicone material. This configuration is advantageous because the firmer rear chamber simulates the pectoralis chest muscles while the softer front chamber moves like a natural breast. This prosthesis provides a significant natural drape with softness to fill and mold to a brassiere cup completely and naturally. The overall softness of the prosthesis helps the prosthesis mold to the chest wall contributes to redistributing the weight of the prosthesis across and against the chest wall and away from the brassiere shoulder strap.

Subsequent developments led to the introduction of attachable prostheses, which could be attached to the skin of the wearer. Like the earlier silicone prostheses, the attachable products included a single volume of a two-component cross-linked silicone material contained within a cavity formed by two pieces of polyurethane film. The prosthesis is held in place on the wearer's chest by a skin support or fastening slab, which has a skin-friendly adhesive on one side and attachment members on the other side. The prosthesis is attached to the skin support by complementary attachment members. U.S. Patent Nos. 5,071,433 to Naestoft et al. and 5,352,307 to Wild describe attachable prostheses that employ hook-and-loop fasteners, where the hook material is on the prosthesis and the loop materials forms one side of the skin support.

Although many women are able to be fitted with the types of products described above, there are many mastectomy patents who, due to variations in their surgery, their size, or other factors, are more difficult to properly fit with off the shelf external prostheses. This has resulted in the introduction of custom fitted external breast prostheses.

The custom breast prostheses that have been previously available suffer from several drawbacks. First, the fitting requires that a plaster cast be made of the patient's entire chest. Second, the finished product is fairly rigid, and does not look or feel like a natural breast under clothing. In addition, custom breast prostheses are relatively expensive. Despite these drawbacks, custom breast prostheses provide the best alternative for some mastectomy patients.

Therefore, there is a need in the art for an improved system and method for fitting, designing, and manufacturing custom external breast prostheses. The improvement should provide a custom breast prosthesis that duplicates the form, feel, weight distribution, fullness, and softness of the patient's natural breast as closely as possible, while remaining affordable to the majority of mastectomy patients.

SUMMARY OF THE INVENTION

The present invention provides a system and method for designing and manufacturing a custom breast prosthesis. The invention employs novel methods, materials, and apparatus to improve the design and manufacturing processes associated with the production of custom breast prostheses. The invention results in a custom breast prosthesis that provides mastectomy patients with a viable alternative to surgery while duplicating as much as possible the look and feel of the natural breast under clothing. The present invention provides a method of design and manufacture that allows significant involvement of the patient in order to ensure optimum customer satisfaction while also keeping costs down. The resulting custom breast prosthesis is highly durable and will retain satisfactory fit and appearance even when the patient experiences typical seasonal body changes. Finally, a custom breast prosthesis in accordance with the present invention duplicates the form, feel, weight distribution, fullness, and softness of the natural breast more closely than any other products currently on the market.

The various aspects of the present invention may be more clearly understood and appreciated from a review of the following detailed description of the disclosed embodiments and by reference to the appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a flow chart of an exemplary method of designing and manufacturing a custom breast prosthesis.

Fig. 2 illustrates an exemplary blank, which is used to form a mandrel.

Fig. 3 illustrates a mandrel formed from the blank of Fig. 2.

Fig. 4, consisting of Figs. 4a and 4b, illustrates a base for the mandrel of Fig. 3, and the base/mandrel combination, respectively.

Fig. 5 is a cross-sectional view of a compensated and uncompensated mandrel.

Fig. 6 illustrates a wax dam that is used to form a mold cavity.

Fig. 7 illustrates the back side of a mandrel after it has been compensated.

Fig. 8 illustrates a polycarbonate floating plate used to form the back side of a prosthesis.

Fig. 9 illustrates a bag sealing die.

Fig. 10 illustrates a bag attached to the mold.

Fig. 11 illustrates a clamp assembly used to hold the mold during the curing process.

Fig. 12 is a flow chart of an alternative method of designing and manufacturing a custom breast prosthesis using computer aided design techniques.

DETAILED DESCRIPTION OF THE INVENTION

The present invention will now be described with reference to the drawings, in which like numerals represent like elements throughout the several views. A custom breast prosthesis designed and manufactured in accordance with the present invention employs an improved process to provide an external breast prosthesis that duplicates the form, feel, weight distribution, fullness, and softness of a patient's breast as closely as possible, while remaining affordable to the majority of mastectomy patients. In general, the advantages of the present invention result from both the materials and processes employed in the design and manufacture of the custom breast prosthesis.

The process of producing a custom breast prosthesis in accordance with the present invention comprises two processes, a design process and a manufacturing process. In one embodiment of the present invention, the design process may be based upon the use of a two-part silicone modeling compound that can be shaped, worked, and sculpted much like modeling clay, but which then cures at room temperature to a hard rubber-like material that can then be carved, sanded, drilled, or machined to provide a final model, or mandrel, of the finished prosthesis. Desirably, the material is non-toxic, hypo-allergenic, and non-irritating when applied to the skin. The use of this type of material allows the designer to sculpt a "physical" mandrel on-site in the presence of the patient, which results in an interactive design process that ensures the best possible fit and appearance. Once a satisfactory mandrel shape is decided upon, the mandrel is sent to the manufacturer. At this point, the design process continues with the mandrel being

compensated for fullness, drape, shrinkage, weight distribution, and attachment system (if any is used).

In this embodiment of the present invention, the manufacturing process begins with the finished mandrel. A mold may be cast from the mandrel using an off-the-shelf silicone molding compound for the cavity, and a backside floating plate thermoformed from a material, such as polycarbonate. The footprint of the mandrel is traced from the mold cavity outline, then converted to a pattern for forming a custom heat sealing die. The heat sealing die is used to make a polyurethane bag, which encloses a silicone gel.

The fill weight for the prosthesis is determined by multiplying the weight of the finished mandrel by a factor. The bag is placed in a filling/sealing jig and filled with uncured silicone gel at the correct softness, color, and volume. The final heat seal is added, and the bag is removed from the jig. The bag is then fastened to the cavity side of the mold, taking care to line the bag seal edge to the edge of the mold cavity. The mold is placed on the mold clamp assembly, and a vacuum is drawn through a tiny hole at the lowest point in the mold to ensure good nipple and undercut detail through the cure. The floating plate, with or without attachment tabs, is placed on the top of the cavity side of the mold; the mold clamp assembly is closed; and the entire assembly is heated in an oven to cure the silicone and chemically adhere the silicone to the bag. A vacuum is applied throughout the cure. When the curing period is over, the mold assembly is removed from the oven and cooled on a ventilated cooling grate. The prosthesis is carefully removed from the mold, trimmed, inspected, and then sent to the retailer to be fitted on the patient.

In a further embodiment of the present invention, the design process may be based upon computer data acquired by scanning the patient's chest using a three-dimensional scanner. In this process, three-dimensional data representing the shape of the patient's chest is acquired and stored in a computer. The physical mandrel mentioned above is replaced by a "virtual mandrel," which is derived from data representing the contour of the chest wall and represents a mirror image of the patient's natural breast. Once this data is acquired, the virtual mandrel is compensated for fullness, drape, shrinkage, weight distribution, and attachment system (if any is used).

In this embodiment of the present invention, the manufacturing process begins with the finished virtual mandrel. A mold insert may be machined directly from the data associated with the virtual mandrel. Preferably, the mold is machined from a reusable metal material in order to increase efficiency and economy. Because the mold is metal, the prosthesis may be cured in normal ovens with other products. Similarly, because the mold is a reusable metal, the mold may be melted down, recast, and eventually machined

again. The data representing each patient's prosthesis is stored electronically, so that the mold itself need not be stored.

Turning now to the flow chart of Fig. 1, the design and manufacturing process employing a physical mandrel will be described in additional detail. As depicted in Fig. 1, an exemplary method **100** begins at step **105** with the manufacture of a "blank," which is modified to form the physical mandrel. The size and shape of the blank may be based on the style and size of the patient's currently worn breast prosthesis. The blank may be made in the same style as the currently worn breast prosthesis, but is typically one size smaller. The blank serves as a starting point for the sculpting session, and is usually prepared prior to traveling to the sculpting site. Two exemplary blanks are illustrated in Fig. 2.

Step **110** represents the on-site sculpting session, which typically takes place at a retailer's shop. At the sculpting site, a designer meets with the patient and discusses the patient's complaints with previous breast prostheses, her preferences regarding fit and appearance, her expectations, etc. This information helps the designer visualize how the finished prosthesis should look, how it will be mated with the chest wall, etc. The patient puts on a bra that best represents the type of bra the patient will typically wear. Those skilled in the art will appreciate that bra selection is very important because the custom prosthesis is designed to fit not only the patient's chest wall, but also to fit a specific type of bra. Therefore, the selected bra style should be the style that best fits the shape of the patient's natural breast, is most flattering to her figure, and provides the best comfort.

After a bra is selected, the patient puts on the bra and remains standing during the sculpting session. A blank is placed in the bra and inspected by the designer and patient. The designer then modifies the blank and places it back in the bra. The blank is modified by adding additional sculpting material to the blank, or by removing sculpting material with a knife, sandpaper, etc. The process of modifying and evaluating the blank may be repeated several times to form a physical mandrel having a satisfactory shape and "footprint." As used herein, the term "footprint" refers to the outline of the prosthesis, which contacts the chest wall. The bra is then removed.

A cosmetic pencil is used to draw an outline of the mandrel's footprint on the chest wall. A release agent, such as petroleum jelly, is applied to the chest wall. An impression material is mixed and applied to the back of the mandrel, which is then lightly pressed against the chest wall and oriented to correspond to the footprint. Any impression materials may be used as long as the material conforms to a patient's chest wall when pressed against the chest wall. The impression material typically cures in five to ten minutes to yield an accurate imprint, or impression, of the chest wall on the back of

the mandrel. The marked footprint outline on the chest wall transfers to the impression material providing a guide for cutting the mandrel to the correct footprint shape.

At this point, the patient again puts on the bra, and the mandrel is placed in the bra. The mandrel is inspected and fine tuned by the designer until a satisfactory shape and fit are achieved. Those skilled in the art will appreciate that the dialogue that takes place with the patient throughout the sculpting session helps ensure the best possible fit and appearance. Because the designer works directly with the patient, anatomical asymmetries, which may be natural or the result of surgery, can be taken into account and compensated for. Traditional plaster casts do not provide sufficient anatomical information to facilitate this type of compensation. This interaction is an important advantage of on-site design and greatly contributes to the finished product being satisfactory to the patient.

Finally, the mandrel is marked for orientation and nipple placement, and nipple measurements are recorded. Color and softness are matched and recorded. The mandrel is then returned to the manufacturing facility. A typical finished mandrel is illustrated in Fig. 3.

The design process continues once the mandrel is returned to the manufacturer. As shown in Fig. 1 at step **115**, a base may be made for the mandrel to provide a support for working on the mandrel. The base also preserves the anatomical curves of the footprint and serves as the base for pouring the mold cavity. The base is illustrated in Fig. 4a. Fig. 4b illustrates the base with the mandrel positioned thereon.

At step **120** of Fig. 1, the mandrel undergoes a compensation process, wherein the mandrel is compensated for a variety of factors. Those skilled in the art will appreciate that the custom breast prosthesis is typically made from a soft silicone gel encased in a polyurethane shell. These materials yield a prosthesis that closely mimics the suppleness and weight of human tissues. However, one drawback is that the final prosthesis will usually deform under the force of gravity as a function of its softness, orientation, fullness, and weight distribution, just as a natural breast does. Also, silicone gel typically shrinks 5-8% during the curing process. Therefore, the mandrel is typically compensated so that the finished prosthesis retains the fit and appearance of the on-site sculpture.

To perform the compensation process, the cup side of the mandrel may be digitized and stored for analysis in a computer aided design (CAD) surfacing program. Designers then determine how the mandrel may be modified to best translate into the finished prosthesis. As before, modification of the mandrel involves adding material to or removing material from the mandrel. Curves which tend to flatten under gravity are given

greater convexity, the projection (how far the prosthesis protrudes) is increased to compensate for "sag" and shrinkage, and fullness is added to regions which might collapse when under the strain of bra fabric. All of these compensations, as well as others, may be done in such a way as to preserve the anatomical contours of the patient's natural breast.

Fig. 5 illustrates the nature of the compensation that may be applied to the mandrel. The dashed line **510** illustrates a cross-sectional view of the mandrel before it has been compensated. The solid line **520** illustrates a cross-sectional view of the mandrel after it has been compensated. The compensation **530** increases the projection (P) of the mandrel by approximately 8 per cent in order to allow for shrinkage and backside hollowing. Drape compensation **540** adds fullness to compensate for the effects of gravity. The back side of the mandrel may be hollowed in order to reduce and redistribute the weight of the prosthesis. A fit gasket **550** may be used to provide a uniform transition to the chest wall. An attachment shelf **560** may be used to provide for placement of an attachment system. The compensation of the back side is discussed below in conjunction with step **130**.

After the mandrel is compensated by adding or removing material, the finished mandrel cup side may be digitized and compared with the original digitized data. After the comparison, additional adjustments may be made to the mandrel if necessary. Once the final cup side appearance is determined, the mandrel is sanded to a smooth surface, and the nipple is added.

After the cup side of the mandrel is finished, the mandrel may be used to create a mold cavity, as shown in step **125** of Fig. 1, which will then be used to form the prosthesis. To form the mold cavity, the mandrel is first sealed to the base with a heavy silicone grease, and covered with a thick layer of a suitable release agent (e.g., petroleum jelly). Wax sheeting with a low softening temperature is softened, and then fashioned around the mandrel/base assembly to provide walls of a "vessel," which is illustrated in Fig. 6. Additional sealing grease is applied where necessary, and a molding compound is mixed and poured into the vessel. Suitable molding compounds include, but are not limited to, a room temperature vulcanization (RTV) silicone molding compound such as Vi-Sil V-242, manufactured by Rhone-Poulenc and available from Medford Silicones, Medford, NJ. The molding compound may be cured for up to about eighteen hours. Following the curing process, the wax is removed the mold is inverted, and the mandrel and base are removed from the cavity. A hole is drilled at the lowest point of the cavity to allow subsequent application of a vacuum. Desirably, the hole is about 1/16 inch in diameter. The cavity side of the mold is now complete, and may be used as a support for the mandrel while the back side (chest wall side) compensation is added.

As shown in Fig. 1, the back side of the prosthesis is compensated at step **130**. First, the back side of the mandrel may be carefully hollowed to reduce weight while maintaining the fit and appearance. Additionally, the weight distribution may be optimized by removing or adding sculpting material to the hollowed areas to ensure that the prosthesis will drape and "flow" just like the natural breast under normal body movements and positions. If an attachment system, such as hook and loop fasteners, is desired, the back side may be modified to accommodate the tabs of hook material. All back side modifications may be done in the way which ensures that the anatomical curve corresponding to the chest wall is preserved, so that the fit of the prosthesis will not be adversely affected. An example of a mandrel with back side compensation completed is illustrated in Fig. 7.

At step **135** of Fig. 1, the "floating plate" is made. As used herein, the term "floating plate" refers to the mold surface that is used to form the back side of the prosthesis. The floating plate usually undergoes a series of modification steps to improve the fit and appearance of the finished prosthesis. For this reason, the floating plate is desirably formed from a thermoformable material. Suitable thermoformable materials include, but are not limited to, polycarbonates, polyimides, and polyamides. Desirably, the thermoformable material is a polycarbonate in order to minimize the cost of materials and labor. In order to form the floating plate, vacuum channels are carved in the surface of the cup side of the mandrel. The vacuum channels extend to the edges of the footprint. The mandrel is placed in the mold cavity, which is then placed on the thermoformer platen so that the vacuum hole in the cavity lines up with the vacuum port of the thermoformer. A thermoformable material, such as polycarbonate sheeting having a thickness of 1/16 inch, is then placed in the thermoformer frame, and subjected to heat and vacuum forces. Thermoforming conditions may vary depending on the materials used and the thermoformer type. For polycarbonate sheeting, desirably the polycarbonate sheeting is dried at about 120°C for a period of about thirty minutes prior to thermoforming, to remove bubbles from the sheeting. Once formed, the floating plate may be trimmed and bead-blasted to prevent adhesion to a prosthesis bag material, such as polyurethane. For illustrative purposes, a polycarbonate floating plate and mold cavity are illustrated in Fig. 8. Thermoforming the floating plate enables fast and inexpensive modifications, if necessary, of the floating plate and ultimately, the final custom breast prosthesis.

In one embodiment of the present invention, a floating plate cover is formed, as shown in step **140** of Fig. 1. The floating plate cover is used in combination with the floating plate to provide support thereto. In the case of larger prostheses, thermoformable materials, such as polycarbonate, may flex or distort. In these cases, an additional support may be added in the form of a floating plate cover. The floating plate cover may

be formed from a molding compound, such as the silicone molding compounds discussed above.

While the floating plate and/or floating plate cover is being formed, a bag for forming the outer surface of the prosthesis may also be fabricated, as shown in step **145** of Fig. 1. The bag may comprise a variety of materials including, but not limited to, polyurethane and silicone polymers. Desirably, the bag material comprises one or more layers of a thin polyurethane film, which has a matte finish on the cup side. The edges of the bag are heat sealed to form a shape defined by a custom sealing die, which is made for each custom prostheses. The outline of the mold cavity may be used as a guide to trace the sealing die pattern, which is then reduced by 3-5% to produce a bag which may be stretched to fit the mold (to prevent wrinkles in the resulting prosthesis). From the pattern, the die may be formed from a material, such as an aluminum stock sheet having dimensions 1/8 x 3/4 inches, on a bending jig so that the 1/8 inch edge forms the seal. The die may be clamped to an universal die mounting plate and the seal edge milled flat. The mounting plate is then mounted into existing bag sealing equipment to form a bag as shown in step **150** of Fig. 1. Numerous bags are typically made to accommodate any iterations, which may be required to produce an acceptable prosthesis. A bag sealing die is illustrated in Fig. 9.

In step **155** of Fig. 1, a bag is fitted with a fill tube and clamped into a filling/sealing jig. The fill weight of the prosthesis is determined by weighing the mandrel, then multiplying by a factor taking into account various factors including the density of the sculpting material, the density of the impression material, and the density of the uncured silicone gel material. Typically, a factor of about 0.7 is used to get the fill weight. From the patient data, the color and softness is referenced, and the bag is filled with an uncured silicone gel. The choice of a particular uncured silicone gel may be made by one of ordinary skill in the art given a patient's particular needs. Suitable silicone gels are well known in the art of making external breast prosthesis, and any one may be used in the present invention. An appropriate silicone rubber material is described in detail in Patzke and Wohlfarth, "Vernetzungssyteme beim Siliconkautschuk," in CHEMIKERZEITUNG 97th year (1973) No. 4, pages 176-180, which is incorporated herein by reference. Once the bag is filled with the uncured silicone gel material, a heat seal is applied to the fill port, and the bag is removed from the jig.

In step **160** of Fig. 1, the mold cavity is preheated to a desired temperature depending on the uncured material used. For uncured silicone, the mold cavity is heated to a temperature of about 160°C. The bag is then fastened to the mold using staples or some other attachment means. While staples are inserted, the bag is stretched around the

perimeter of the cavity such that the inside edge of the bag seal is lined up with the edge of the cavity. The tension of the stretched bag should be fairly uniform to prevent wrinkle formation during the curing process. This is illustrated in Fig. 10. The mold cavity side, with bag in place, is then situated on the mold clamp assembly as shown in step **165** of Fig. 1. The mold clamp assembly may consist of a lower platen fitted with a vacuum port, and an upper, spring-loaded, platen, which clamps the two mold pieces together. The springs allow the floating plate to "float" in response to expansion of the silicone gel during cure. The mold cavity piece is oriented such that its vacuum hole lines up with the platen's vacuum port, and a vacuum of about 21" Hg is applied. The vacuum draws the bag into the mold, ensuring good nipple and undercut detail. The floating plate is then lined up and mounted on top of the mold cavity along with floating plate cover, if any, and the top platen is secured and clamped down, allowing some play to accommodate expansion of the gel. If attachment tabs are to be used, they are fastened to the floating plate (typically with Velcro tabs) and coated with adhesion promoter prior to mold assembly. The entire mold assembly is then placed in the oven and cured as shown in step **170** of Fig. 1. The curing process conditions may vary as desired. Typically, the curing temperature is from about 140°C to about 160°C and the vacuum remains in place during the curing process. An exemplary clamp assembly is illustrated in Fig. 11.

After the curing process is completed, the mold assembly is removed from the oven and cooled. The prosthesis is carefully removed from the mold and trimmed around the edge seal as depicted in step **175** of Fig. 1. The prosthesis is cleaned and inspected for bag seal, gel adhesion, fastener tab adhesion, leaks, punctures, cosmetics, etc. If satisfactory, the prosthesis is tested for drape, fit, appearance as it will be worn, etc. on a mannequin or similarly curved surface. If changes are needed, such as to the floating plate, the mandrel is modified and a new floating plate is thermoformed. A new prosthesis is then made via the above-described procedure.

Once the process is complete, the custom prosthesis may be packaged in custom packaging, with a cradle formed directly from the mandrel as shown in step **180** of Fig. 1.

At step **185** of Fig. 1, the completed prosthesis is fitted on the patient. The patient is fitted with the bra used during the design session. The prosthesis is placed in the bra and oriented as it will be worn. It is inspected for fit and appearance, and the patient is interviewed to determine that the prosthesis is comfortable (not too heavy, not rubbing against sensitive areas, etc.) -

Those skilled in the art will appreciate that the sculpting material used during the initial fitting enables a successful on-site design of the custom breast prosthesis. The

sculpting material makes possible the designer-patient design partnership, which results in a superior product. In one embodiment of the present invention, the sculpting material comprises a silicone composition, which has been rheologically optimized for ease of working and sculpting with hands. Desirably, the sculpting material is odorless, hypo-allergenic, non-toxic, and non-irritating when applied to the skin, making it ideal for the on-site design of the custom breast prosthesis. The material cures at room temperature to a hard rubber in about twenty minutes, giving the designer plenty of time to sculpt, while curing soon enough to hold its shape while being test-fitted, cut, or sanded as part of the on-side design session. The sculpting material adheres well to itself and to other silicone materials, such as the impression material. Desirably, the cured material is heat resistant, up to about 400°F, and easily carved, sanded, drilled, machined, etc. The designer typically pre-measures the material into several chunks, mixing them as needed to minimize waste. Any sculpting material may be used in the present invention as long as the material meets the criteria set forth above. Suitable sculpting materials include, but are not limited to, VISCOFLEX™ sculpting material, available from Kohler Medizintechnik, Neuhausen, Germany; Contrast Putty, available from VOCO GmbH, Cuxhaven, Germany; and Contrast Putty Soft, also available from VOCO GmbH, Cuxhaven, Germany.

The impression material, like the sculpting material, may be a silicone composition. Likewise, it is desirably odorless, non-toxic, hypo-allergenic, and non-irritating when applied to the skin. Desirably, the impression material is a medium viscosity, thixotropic material, which can cure at room temperature to yield a highly detailed, hard rubber impression in five to ten minutes. In a preferred embodiment, the impression material adheres well to the sculpting material, and can be easily cut to a desired shape. The impression material may be packaged in a quantity sufficient to cast one or more patients. Mixing may be done with a spatula in about thirty seconds, and material can be applied with a spatula or tongue depressor. Any impression material may be used in the present invention as long as the impression material meets the criteria set forth above. One particular impression material is available under the tradename CLONE™, from Factor II, Tucson, AZ. Other impression materials, which are used in the dental trade and are suitable for the present invention, include, but are not limited to, SOFTFLEX™ impression material, available from Kohler Medizintechnik, Neuhausen, Germany; Contrast Light Regular, available from VOCO GmbH, Cuxhaven, Germany; and Contrast Light Fast, also available from VOCO GmbH, Cuxhaven, Germany.

Together with the sculpting material, the impression material provides the necessary detail to ensure a custom fit of the prosthesis against the chest wall of the

patient, and its speedy cure allows the impression casting process to take place while the patient is standing, which is the preferred position to ensure good fit and appearance.

In a further embodiment of the present invention, the design process comprises the formation of a "virtual" mandrel as opposed to a physical mandrel as described above. In this design process, a three-dimensional scanner or similar device is used to scan the patient's chest and provide three-dimensional chest wall data to a CAD program. The chest wall data is manipulated to form a virtual mandrel, which represents a mirror image of the patient's natural breast and conforms to the shape of the patient's chest wall. The virtual mandrel is then compensated to account for fullness, drape, shrinkage, weight distribution, and attachment system (if any is used). Those skilled in the art will appreciate that the data manipulation and compensation involve manipulating stored computer data, and more importantly, does not require the fabrication of a physical mandrel. Those skilled in the art will also appreciate that the data manipulation associated with creating and compensating the virtual mandrel may be performed by a designer or CAD operator, or may be automated and carried out by the computer.

After the virtual mandrel is complete, the three-dimensional data that defines the shape of the mandrel may be used to control automatic machine tools, such a computational numerical control (CNC) milling machine, which may be used to form the mold for the prosthesis. Preferably, the equipment machines a cavity mold insert and a floating plate mold insert, which are inserted into a mold fixture. The inserts are desirably machined from a piece of reusable metal material, such as an alloy of tin and lead, or tin and bismuth. Such materials preferably have a melting point of less than about 500°F. This allows the mold inserts to be melted down and machined again after they are no longer needed. This approach also does away with any need to store molds for later use. Once a project is complete, the computer data is stored in case it is needed to make additional prostheses for the patient. Then the metal mold inserts may be melted down and the material reused for other molds.

The scanning-based custom breast prosthesis process replaces many of the manual steps of forming a mandrel with computer aided design techniques. In addition to a three-dimensional scanner, the following process components are desirably used to produce a custom breast prosthesis of the present invention: a computer aided design/computer aided machining (CAD/CAM) software package, a CNC mill, and a reusable metal alloy for moldmaking. The design process enables the production of a custom breast prosthesis, which provides improved comfort and fit to the patient, as well as a substantially identical look compared to the patient's natural breast. This embodiment of the present invention is detailed in the flowchart of Fig. 12.

As depicted in Fig. 12, an exemplary method **200** begins at step **205** of Fig. 12. The patient is fitted with an appropriate bra. The bra style is purely of the patient's choosing, but should be selected and sized for best fit and comfort. Using color samples, the prosthesis color is match to the natural skin tone. Alternatively, a scanner may be purchased, which is equipped with a color CCD (charge coupled device containing) camera, which records a texture map of the patient while scanning. This texture map will record color, skin features, areola and nipple features, etc. as part of the scan. Finally, the patient is screened by the designer for preferences relating to attachment system, if desired, lifestyle, and other design related preferences.

Once the bra is selected, the patient remains in a stationary position by standing against a wall, or secured by other means, such as VELCRO™ straps, in a comfortable position. As shown in step **210** of Fig. 12, the existing breast side of the torso is scanned with the bra on for about 5 to 10 minutes. While still stationary, the bra is carefully removed and the mastectomy side is also scanned for about 5 to10 minutes as shown in step **215**.

Desirably, the scanner is capable of dynamic positioning over a wide range of motion in 3-D space. The scanner system should be able to pick up udercuts of the breast and capture data under the arms. A suitable system for use in the present invention is called the MODELMAKER™ and is manufactured by 3-D Scanners Ltd. of London, England. The MODELMAKER™ can be mounted to a 3-D digitizer arm, such as the FaroArm® made by Faro Technologies, Lake Mary, FL, to yield a freely orientable and portable system. The MODELMAKER™ is supplied with computer software, which will store data points from the scan to produce a 3-D "point cloud." From the point cloud, a 3-D surface model may be produced. The surface model can then be converted to cross-sectional curves for direct output to a CAD/CAM software program, such as sold by Imageware (Ann Arbor, MI) under the product name, SURFACER™, or as sold by Surfware (Westlake Village, CA) under the product name, SURFCAM™. Alternatively, the surface model may be directly exported to the CAD software. Once in the CAD software, the design rules may be applied to produce the final prosthesis design, from which toolpaths may be generated for export to a CNC mill for machining of the mold cavity and floating plate.

Once the breast side and mastectomy side have been scanned and the generated data has been inputted into the computer software, the two scans are merged together to yield a representation of both sides of the torso, as shown in step **220** of Fig. 12. In many cases it will not be necessary to scan the entire torso, only those areas directly involved in the design process. In step **225**, anatomical landmarks are identified and marked in the scan

data. Examples of anatomical landmarks include, but are not limited to, nipple placement, sternum, collarbone, hips, and navel. This information is used later in the design process to position the prosthesis design and determine symmetry. This data may be stored in the final scan file, which is sent to the factory either on hard media or over a phone line, internet, etc.

At the factory, the scan data is refined within the scanning software as a surface model, then exported in a suitable format to a CAD software. The designer studies the transition between the natural breast and the torso, and using CAD tools, trims a copy of the remaining breast from the torso. Using the anatomical landmarks, the trimmed breast is mirrored to the mastectomy side as shown in step **230** of Fig. 12, and inspected for the proper position and conformation. As this mirrored breast model will not mate perfectly with the surgery side chest wall, CAD tools are applied to trim and extend the surfaces until a good transition between breast and chest wall is established, as shown in step **235**.

Using the design/compensation rules described earlier, the front side of the virtual mandrel is compensated for projection, drape, nipple placement, and fullness under the stresses of gravity and the bra, as shown in step **240** of Fig. 12. Using the intersection of the designed front side of the virtual mandrel and the scanned data of the chest wall, the area under the 3-D prosthesis is trimmed from the chest wall. Using the front side design and this area as references, the backside design/compensation rules are applied to design the backside features, such as the fit gasket, attachment shelf, and the proper level of hollowing and ballast to yield the prosthesis' backside design. The backside design step is shown in step **245** of Fig. 12. Those skilled in the art will appreciate that these design features enable the production of a custom breast prosthesis having a lifelike fit and appearance using soft materials such as silicone gels.

Once the design process is completed, a CAM software, or a CAM module contained in many CAD softwares, is used to generate toolpaths for use by a CNC mill, as depicted in step **250** of Fig. 12. Many of the currently available CAM softwares are "smart," meaning that the generation of toolpaths may be carried out with some level of automation, using a known set of parameters, such as the dimensions of available tools in the tool changer, material specifications, and allowable tolerances. The software uses this information to calculate feed rates, best toolpaths and tooling selection, to generate a simulation of the final machining. Those familiar with the art will understand that such features are common to modern CAM software programs.

In step **255** of Fig. 12, a mold "blank" of the appropriate size is cast from a low melt temperature metal alloy. Suitable metal alloys include, but are not limited to, alloys such as tin/lead and tin/bismuth based systems. The "blank" comprises a preformed

cavity and a preformed floating plate, which helps reduce machining time. Those skilled in the art will understand that the above-described blanks may be pre-designed in a number of generalized shapes and sizes. The appropriate blank type chosen for a particular patient may be determined by measuring pre-defined parameters of the CAD design, such as minimum radius, projection depth, etc. As shown in step **260**, the mold is then machined by a CNC mill, using the toolpaths generated earlier. The softness of the melt alloy provides a speedy machining rate. Further, the metal molds do not require preheating and may be placed in normal curing ovens with other products.

After machining, the mold is finished by polishing and/or sandblasting as shown in step **265** of Fig. 12. A vacuum hole is then drilled at the apex of the nipple. The resulting mold pieces form a mold cavity and corresponding floating plate, which can be inserted into a mold fixture. A suitable mold fixture comprises features including, but not limited to, a means of closure, a port for filling a bag in the mold, a suspension system for the floating plate, a clamp for the bag, a port for the drawing of a vacuum, and means for securing the mold pieces. Such a fixture may be constructed in a variety of sizes corresponding to a range of prosthesis sizes typically encountered. The finished mold pieces are inserted and secured into the mold fixture as shown in step **270** of Fig. 12.

Step **275** of Fig. 12 designates a bag-forming step. Bags may be made using the same techniques used in the physical mandrel process described above. Once formed, the bag is placed in the mold fixture as shown in step **280** of Fig. 12. After the bag is secured in the mold fixture, the bag is filled via a fill port, and drained of any air bubbles. The fill port is then heat sealed as noted in step **285**. As discussed above in the manual process, attachment devices such as VELCRO™ strips may be affixed to the floating plate for incorporation onto the custom breast prosthesis, if desired. The mold is closed and clamped for the final curing step as shown in step **290** of Fig. 12.

As discussed above, an additional automation feature may entail a custom color choice, which may be programmed as a pre-set feature into a computer controlled mixing/filling pump. The selected color data may be taken from a database and stored in an RF tag to be placed on the mold. When filling is to be done, the operator scans the RF tag with an RF sensor at the pump, which automatically mixes into the mold cavity the appropriate color components. The mold assembly is then loaded into a curing oven, and cured for the appropriate time and temperature, which varies as a function of prosthesis size. Although curing times and temperatures may vary depending on the prosthesis size and prosthesis components, the curing time typically ranges from about 15 to about 30 minutes at a temperature ranging from about 140°C to about 160°C.

Once the mold is cooled, the prosthesis is removed, inspected, and trimmed as shown in step **295** of Fig. 12. The mold pieces may be removed and re-melted for use in future prostheses as noted in step **300**, since the prosthesis design information for each patient remains in the computer, should a new prosthesis be made in the future or a redesign be necessary due to body changes, etc. Typically, however, the mold pieces remain intact until a final fitting has been successfully carried out.

The finished prosthesis is packaged as noted in step **305** of Fig. 12. The prosthesis may be shipped to a retailer/boutique for the final fitting as shown in step **310**.

The processes described above may be used to form a variety of custom breast prosthesis. In one embodiment of the present invention, a custom breast prosthesis is produced, which comprises a highly compliant silicone gel adhered to and enveloped by a durable polyurethane skin. The silicone gel may be formulated in a variety of colors and degrees of softness to closely match the skin tone and softness of the individual's natural breast. The gel, when cured in a mold, will hold virtually any shape and its density closely duplicates that of the natural breast. Furthermore, the gel quickly heats to body temperature and has a high heat capacity, allowing it to retain that heat even if environmental conditions change.

In another embodiment of the present invention, a custom breast prosthesis is produced, which comprises a polyurethane skin that encloses the silicone and is very thin, yet highly resistant to puncture and abrasion. The polyurethane is stain resistant and washable. A variety of attachment systems, such as hook-and-loop fasteners, are easily adhered to the polyurethane skin to provide a durable and reliable means of attaching the prosthesis to the chest wall. Suitable attachment systems include, but are not limited to, those disclosed in U.S. Patents Nos. 5,071,433 to Naestoft et al. and 5,352,307 to Wild, both of which are incorporated by reference in their entirety.

From the foregoing description, it will be appreciated that the present invention provides a system and method for designing and manufacturing a custom breast prosthesis. The resulting product provides a superior fit and feel, while remaining affordable to the majority of mastectomy patients. Those skilled in the art will appreciate the significant labor time and cost reductions resulting from a repeatable computer aided design process, and the significant materials cost reductions resulting from reusable mold materials. These cost and time reductions yield a commercially viable, fully customized breast prosthesis, which is substantially similar to the patient's natural breast. Further, those experienced in the art will further appreciate that the above-described process may be modified for mass production of customization products, using scanned data to select from a variety of pre-designed and sized prosthetic components.

Having thus described the invention, numerous changes and modifications thereof will be readily apparent to those having ordinary skill in the art, without departing from the spirit or scope of the invention.

Claims

What is claimed is:

1. A method of making a custom breast prosthesis comprising:

scanning a patient's chest wall with a three-dimensional scanner to obtain a first set of data;

forming a visual mandrel from the first set of data using a computer aided design software program;

forming a mold from the visual mandrel; and

molding a composition in the mold to form the custom breast prosthesis.

2. The method of Claim 1, further comprising:

scanning a patient's natural breast with a three-dimensional scanner to obtain a second set of data; and

comparing the first set of data and the second set of data to form the visual mandrel using a computer aided design software program.

3. The method of Claim 2, wherein the first set of data represents a first three-dimensional surface model of the chest wall and the second set of data represents a second three-dimensional surface model of the natural breast, and wherein the first surface model and the second surface model are merged to form a third three-dimensional surface model of the visual mandrel.

4. The method of Claim 3, wherein the visual mandrel is subjected to conformation rules to modify one or more features of the visual mandrel including projection depth, drape, nipple placement, and outer dimensions.

5. The method of Claim 1, further comprising:

comparing the first set of data and a set of data stored in a computer to form the visual mandrel using a computer aided design software program.

6. The method of Claim 1, wherein the mold comprises a preformed mold cavity and a preformed floating plate, both of which are formed from a low melt

temperature metal alloy, which may be melted and reused in a future custom breast prosthesis forming process.

7. The method of Claim 1, wherein the preformed mold cavity and the preformed floating plate are modified in a computational numerical control (CNC) milling machine using toolpaths generated from the visual mandrel design to form a mold cavity and a floating plate.

8. The method of Claim 7, wherein the mold cavity has a mold surface which conforms to an outer surface of the visual mandrel, and the floating plate has a floating plate surface which conforms to an inner surface of the visual mandrel.

9. The method of Claim 1, wherein the visual mandrel undergoes an interactive modification step, wherein the interactive modification step comprises an interactive exchange of information between the patient and a computer aided design operator.

10. A custom breast prosthesis formed by the method of Claim 1.

11. A method of making a custom breast prosthesis comprising:

forming a physical mandrel during an interaction sculpting step, wherein a patient and a designer interact with one another to sculpt the shape of the mandrel;

forming a mold from the mandrel; and

molding a composition in the mold to form the custom breast prosthesis.

12. The method of Claim 11, wherein the physical mandrel is formed by modifying a blank during the interactive sculpting step, wherein the interactive sculpting step comprises an interactive exchange of information between the patient and the designer, and at least one step selected from (1) adding sculpting material to the blank; and (2) removing sculpting material from the blank.

13. The method of Claim 11, further comprising:

forming the physical mandrel with an outer cup surface, an outer periphery, and a cavity, wherein the cavity is capable of covering a portion of a patient's torso;

forming a conformable layer of impression material on a surface of the cavity;

pressing the conformable layer of impression material against the patient's torso to form an inner surface on the physical mandrel, wherein the inner surface substantially mimics a shape of the torso.

14. The method of Claim 11, wherein the physical mandrel undergoes a compensation process comprising at least one step selected from adjusting a projection depth of the physical mandrel; adjusting the outer or inner surfaces of the mandrel; applying a fit gasket to the inner surface; and incorporating an attachment shelf on the mandrel.

15. The method of Claim 11, wherein the mold comprises a mold cavity and a floating plate.

16. The method of Claim 15, wherein the mold cavity has a mold surface which conforms to the outer surface of the physical mandrel, and the floating plate has a floating plate surface which conforms to the inner surface of the physical mandrel.

17. The method of Claim 15, wherein the floating plate comprises a thermoformable material.

18. The method of Claim 15, wherein the thermoformable material is a polycarbonate.

19. A custom breast prosthesis formed by the method of Claim 11.

20. A custom breast prosthesis formed by a method, wherein the method comprises:

scanning a patient's chest wall with a three-dimensional scanner to obtain a first set of data;

forming a visual mandrel from the first set of data using a computer aided design software program;

forming a mold from the visual mandrel; and

molding a composition in the mold to form the custom breast prosthesis.

21. The custom breast prosthesis of Claim 20, wherein the method further comprises:

scanning a patient's natural breast with a three-dimensional scanner to obtain a second set of data; and

comparing the first set of data and the second set of data to form the visual mandrel using a computer aided design software program.

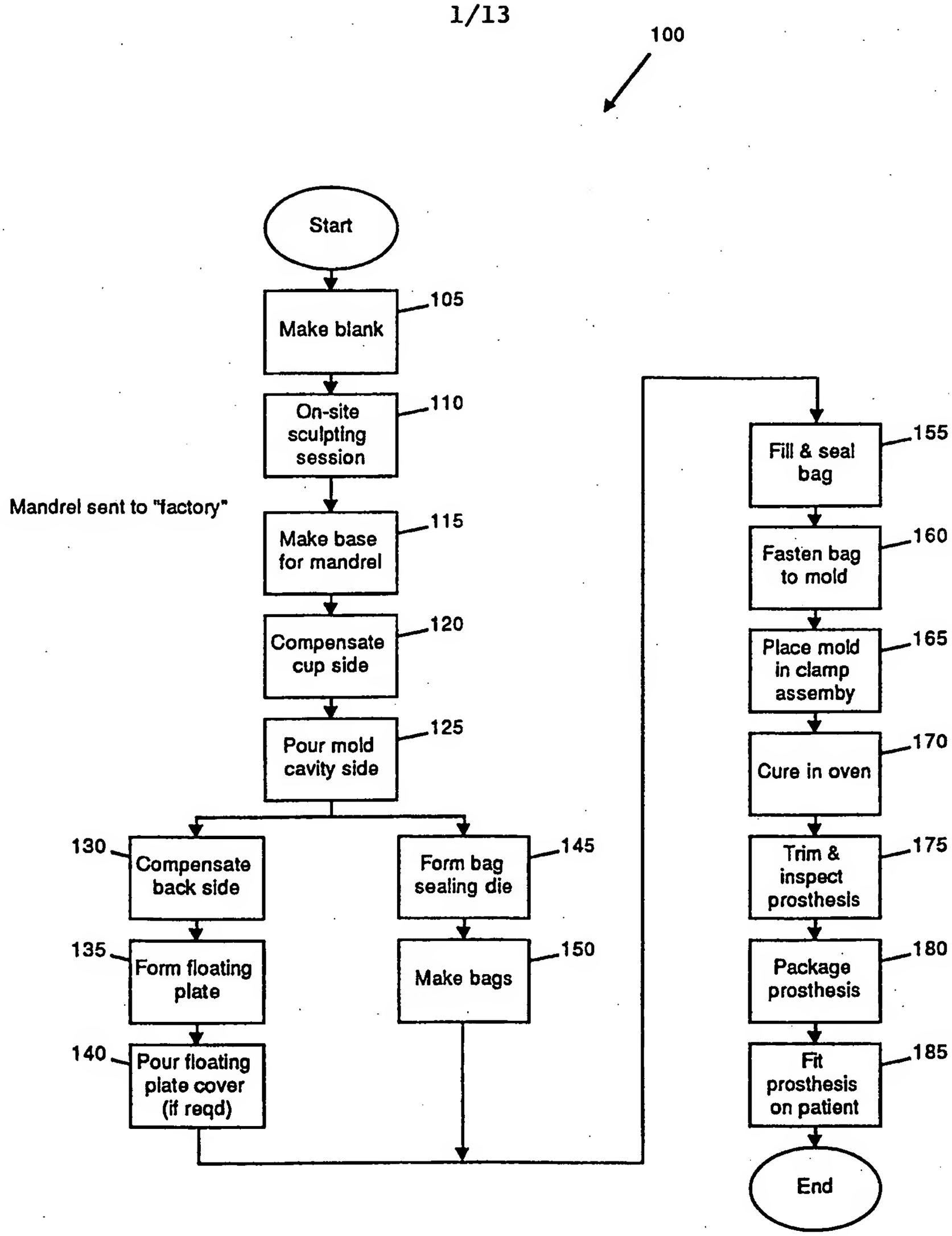
100
Start
Make blank
105
On-site sculpting session
110
Mandrel sent to "factory"
Make base for mandrel
115
Compensate cup side
120
Pour mold cavity side
125
130
Compensate back side
135
Form floating plate
140
Pour floating plate cover (if reqd)
145
Form bag sealing die
150
Make bags
155
Fill & seal bag
160
Fasten bag to mold
165
Place mold in clamp assemby
170
Cure in oven
175
Trim & inspect prosthesis
180
Package prosthesis
185
Fit prosthesis on patient
End

Fig. 1

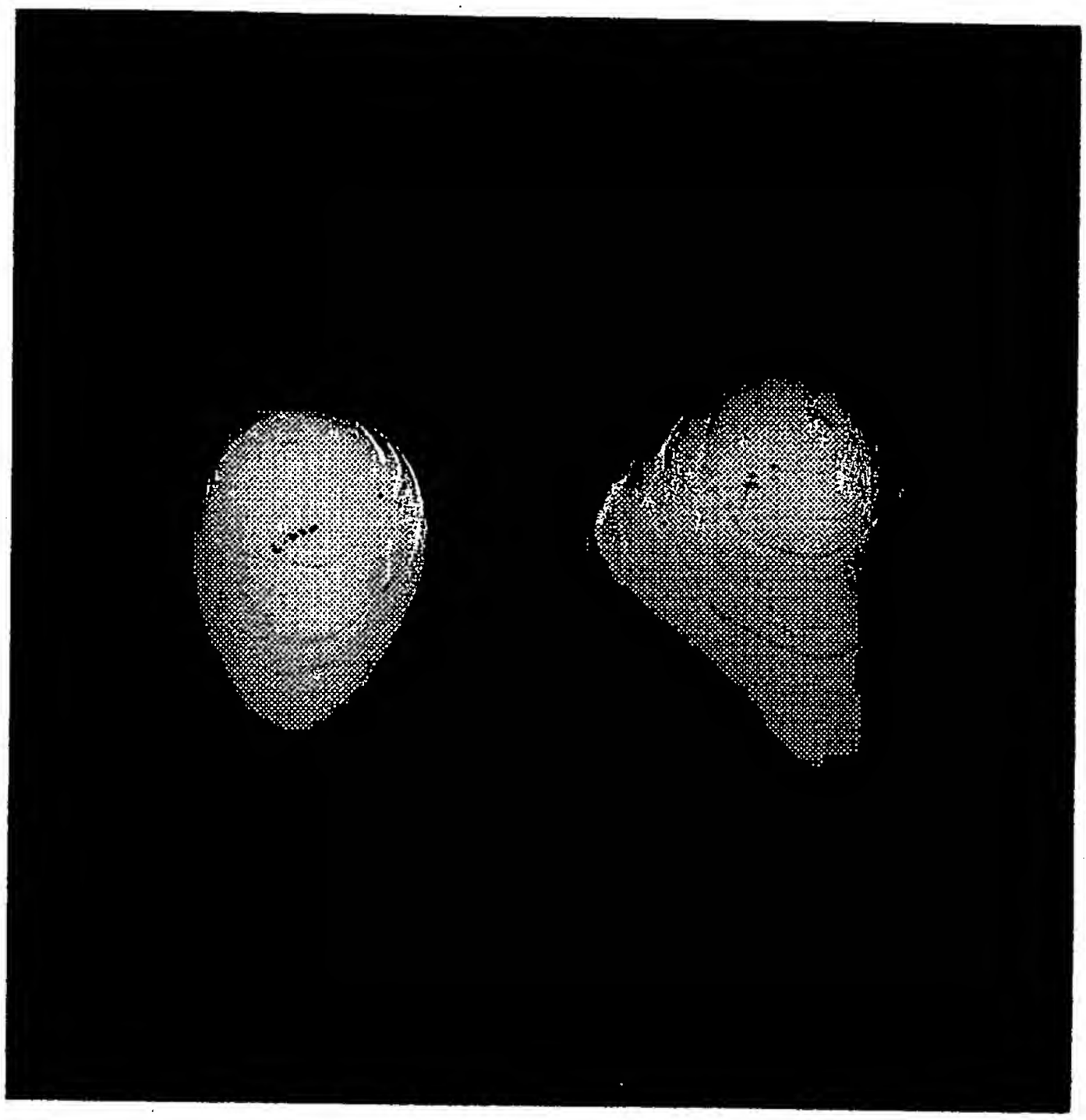

Fig. 2

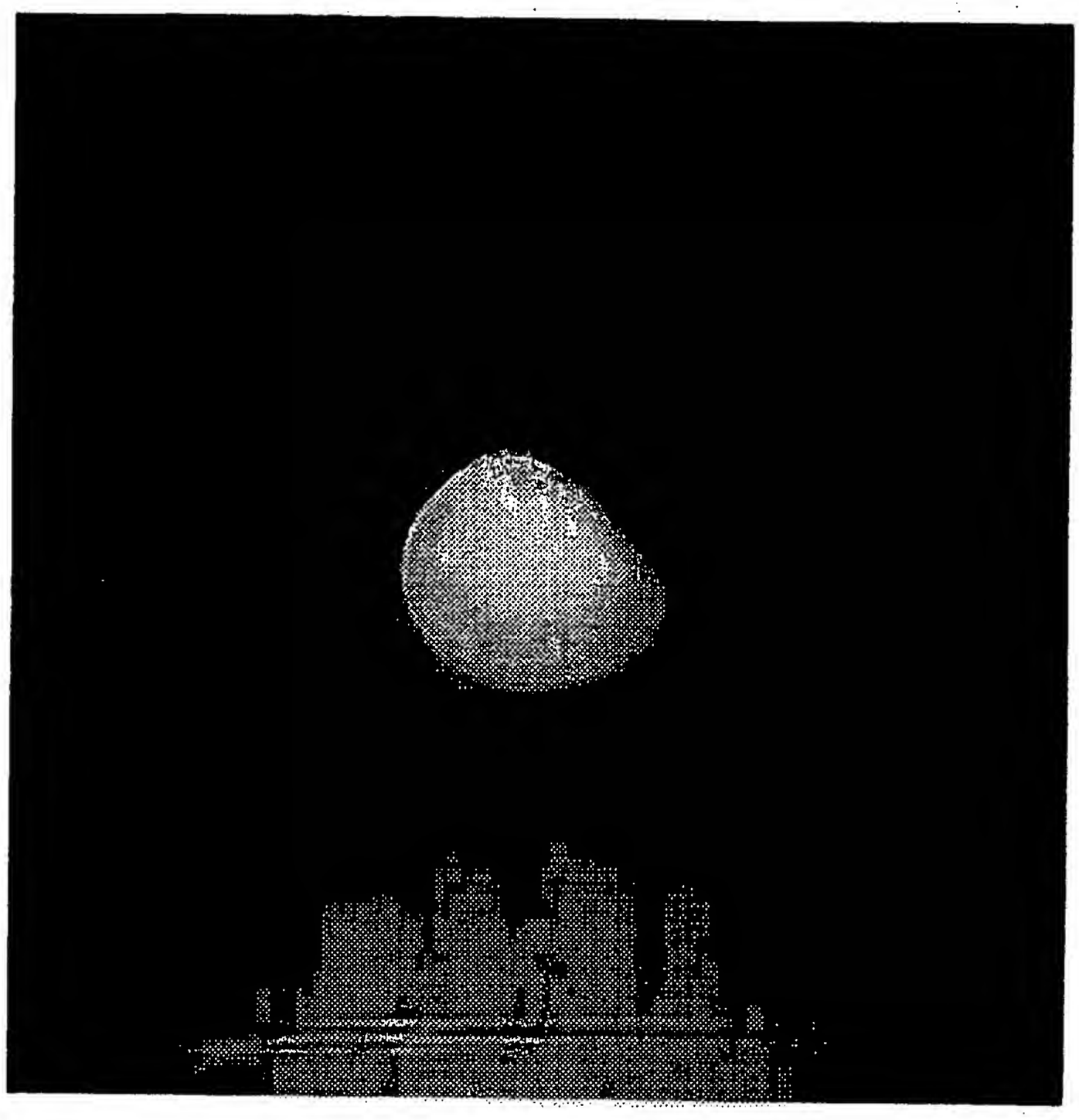

Fig. 3

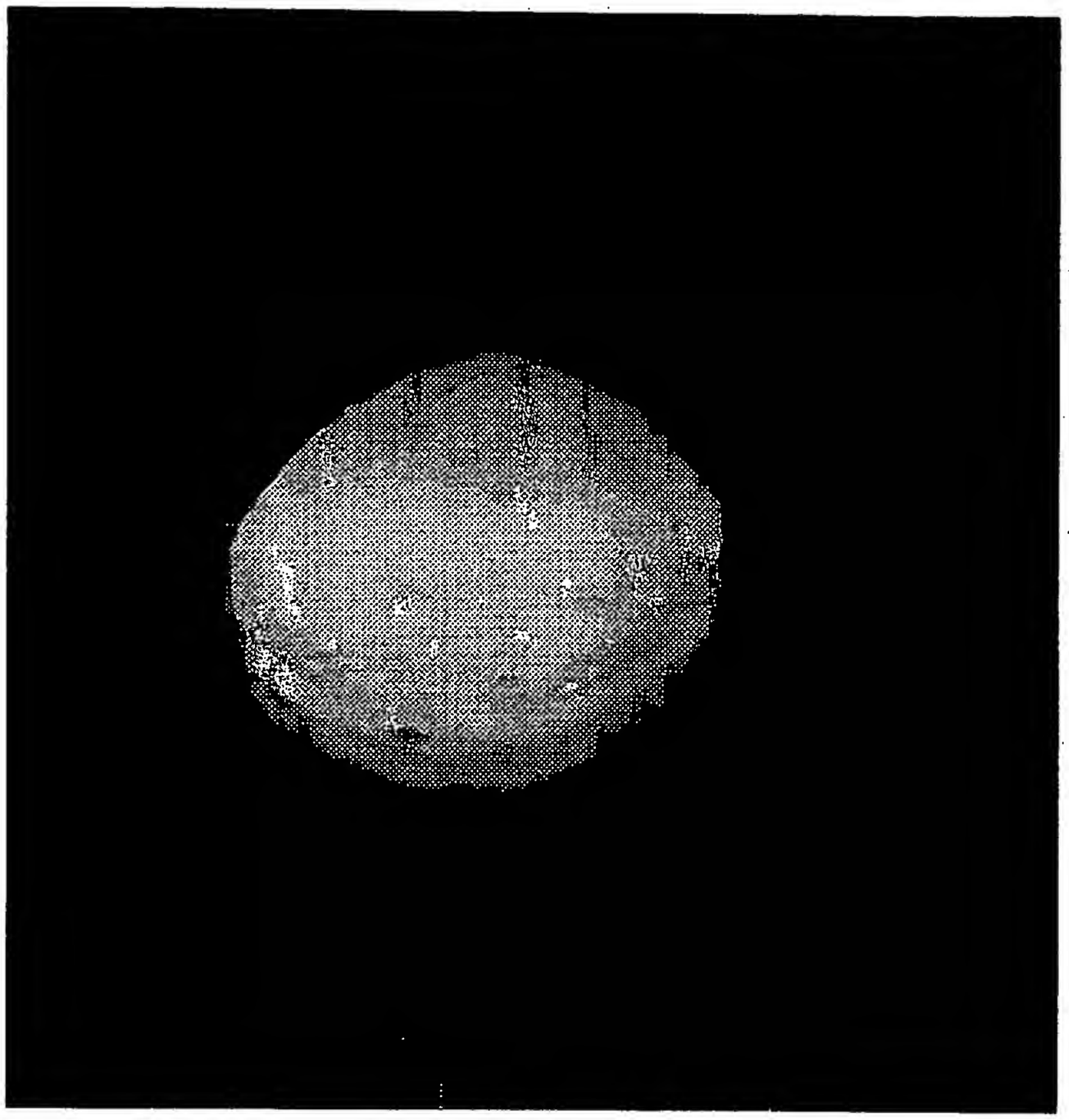

Fig. 4A

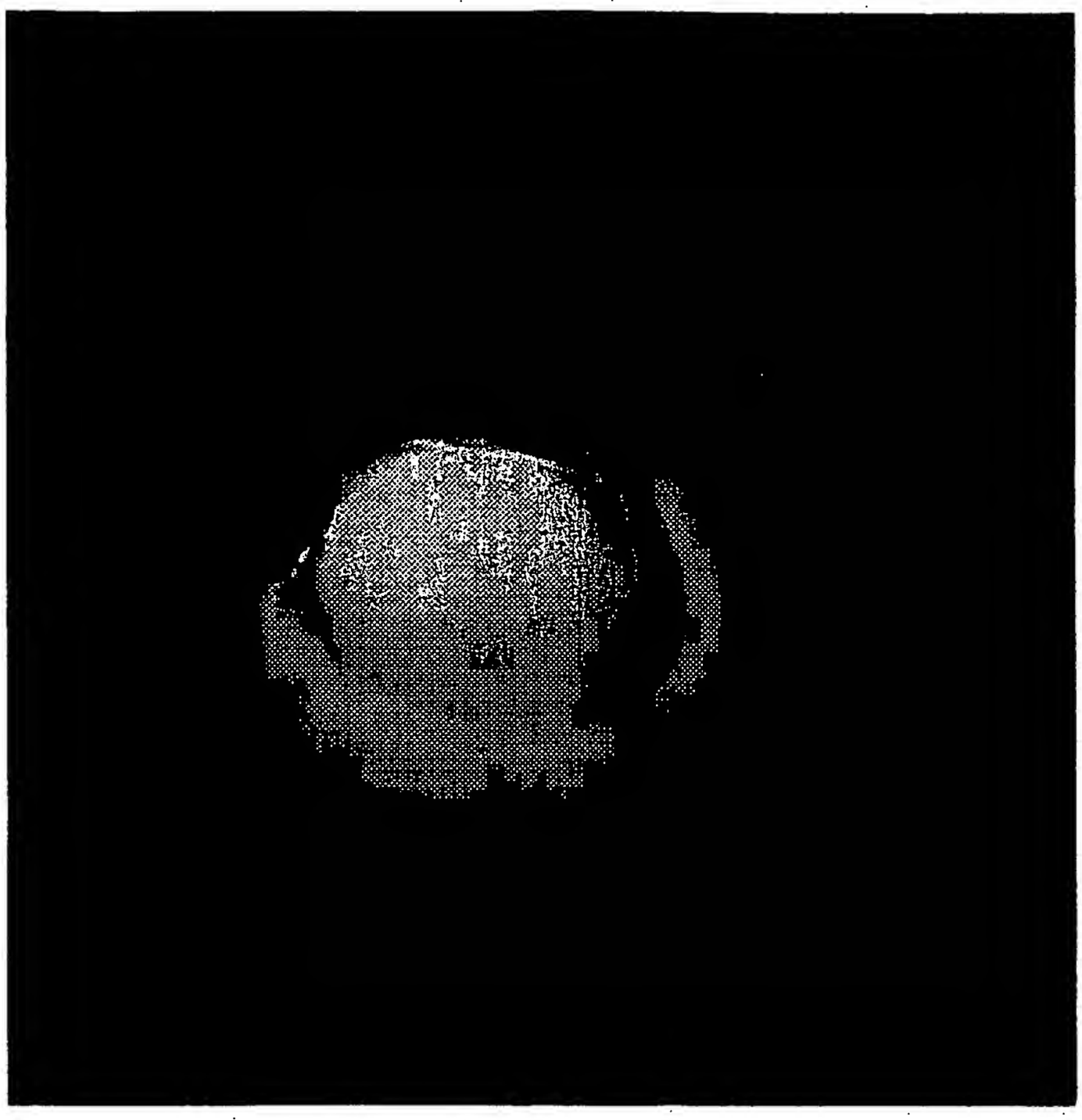

Fig. 4B

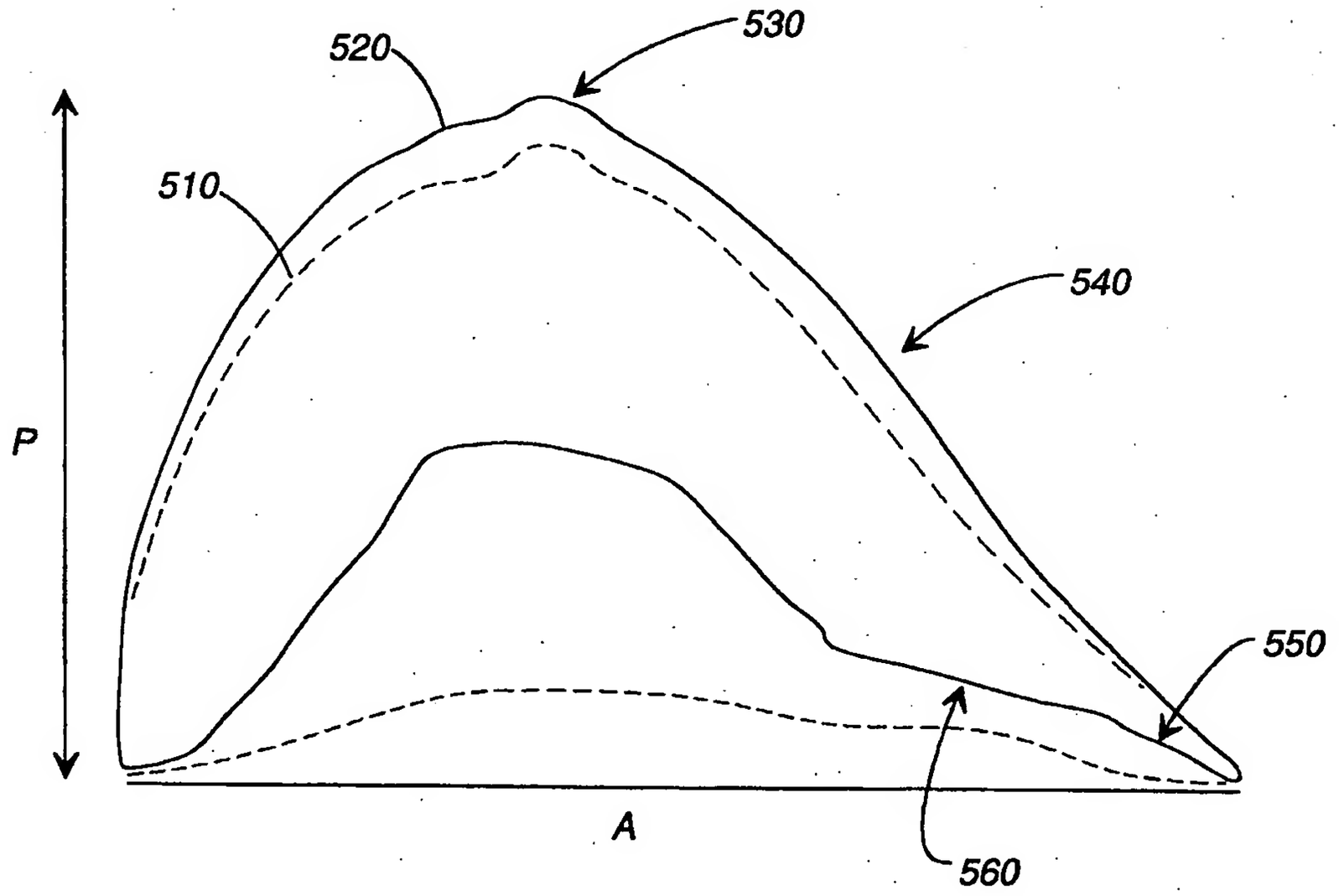

FIG. 5

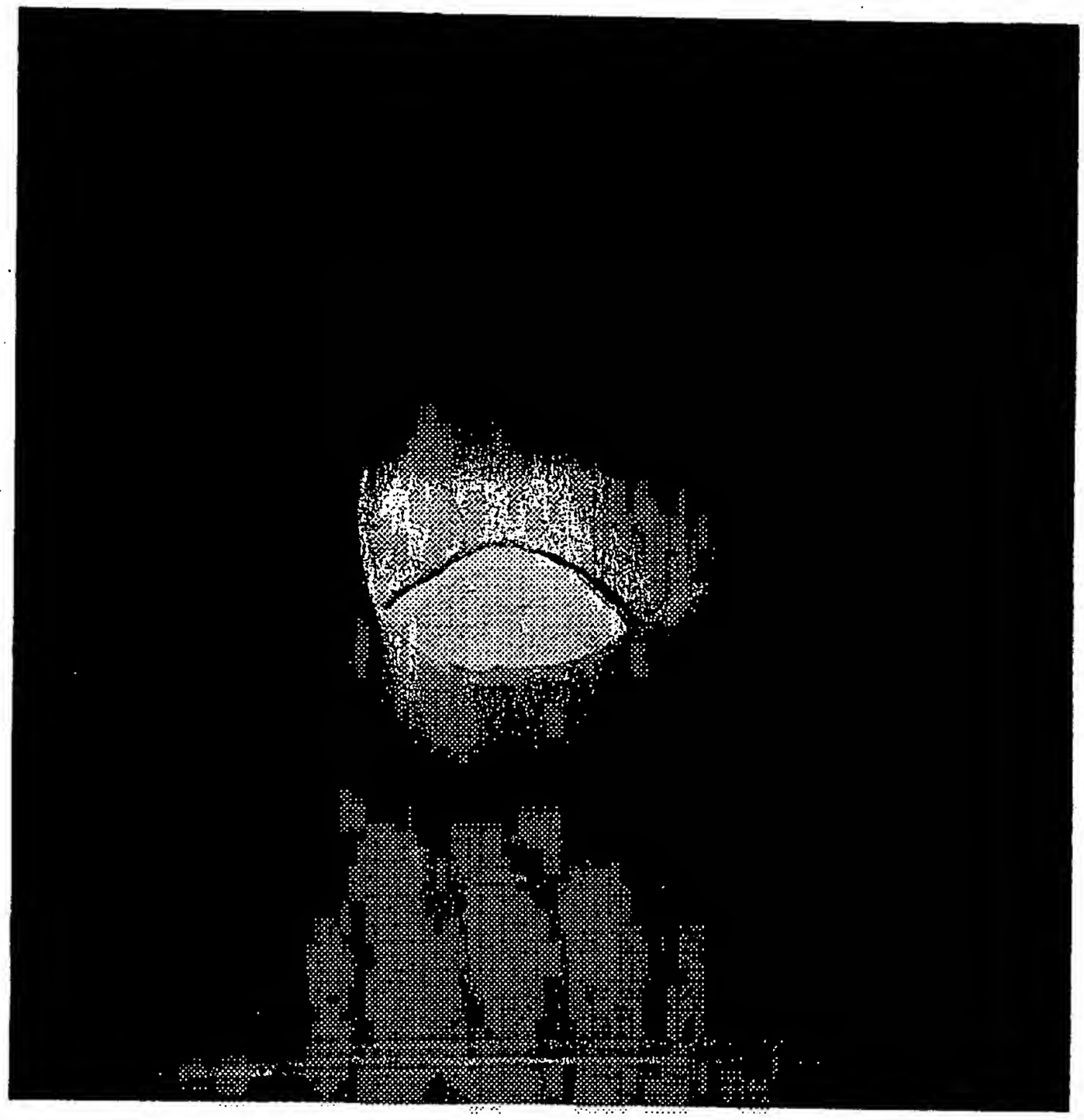

Fig. 6

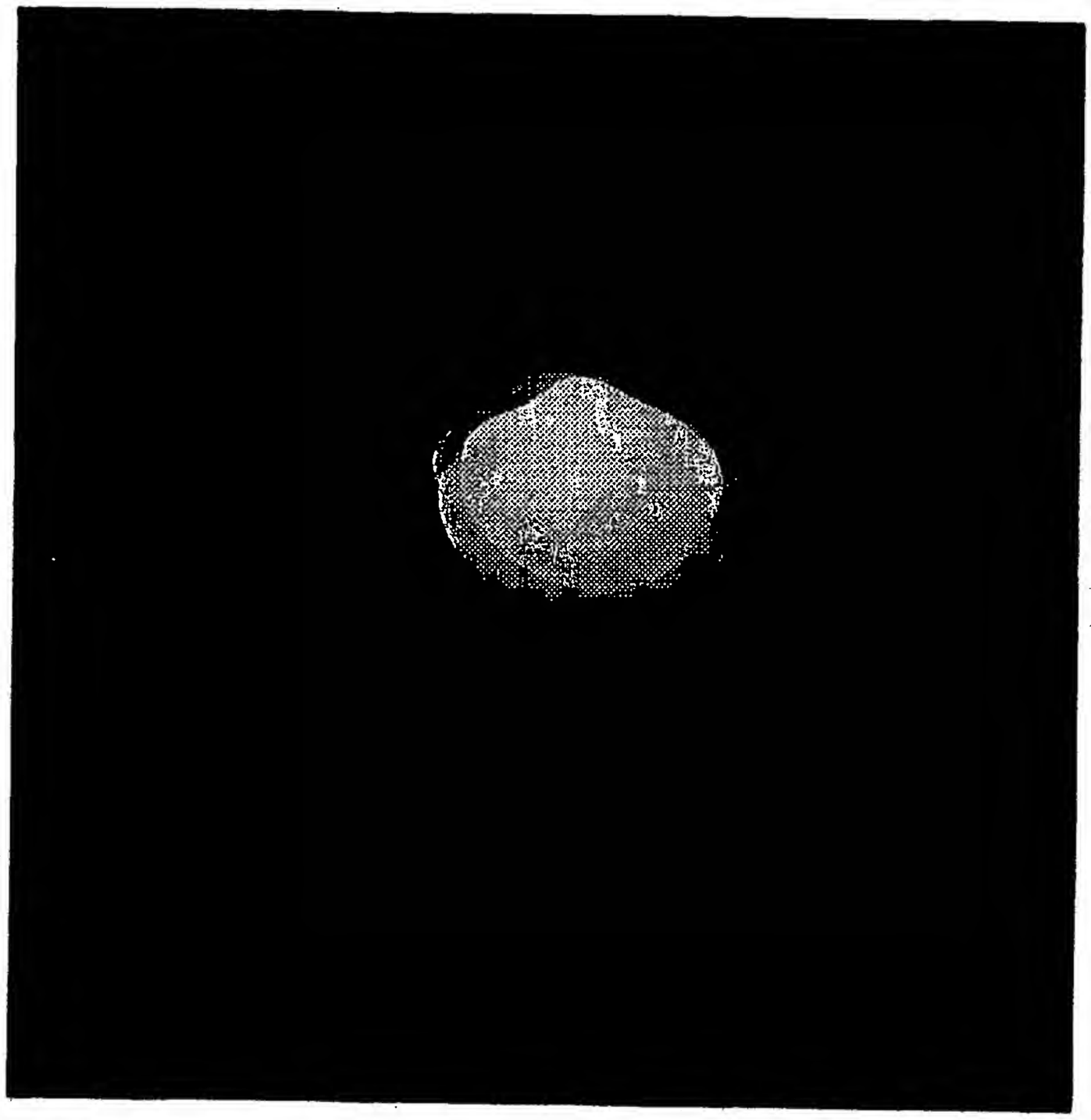

Fig. 7

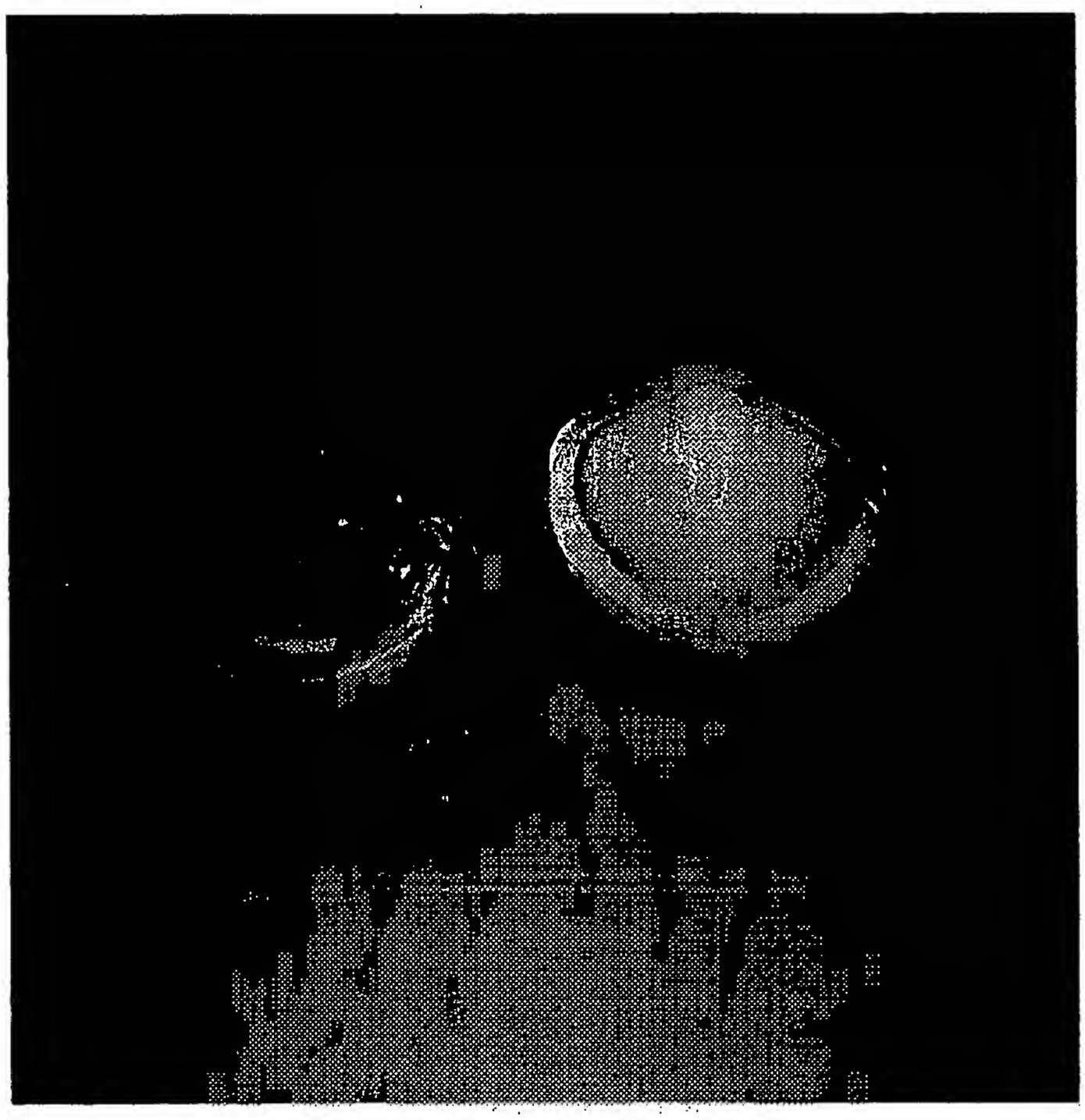

Fig. 8

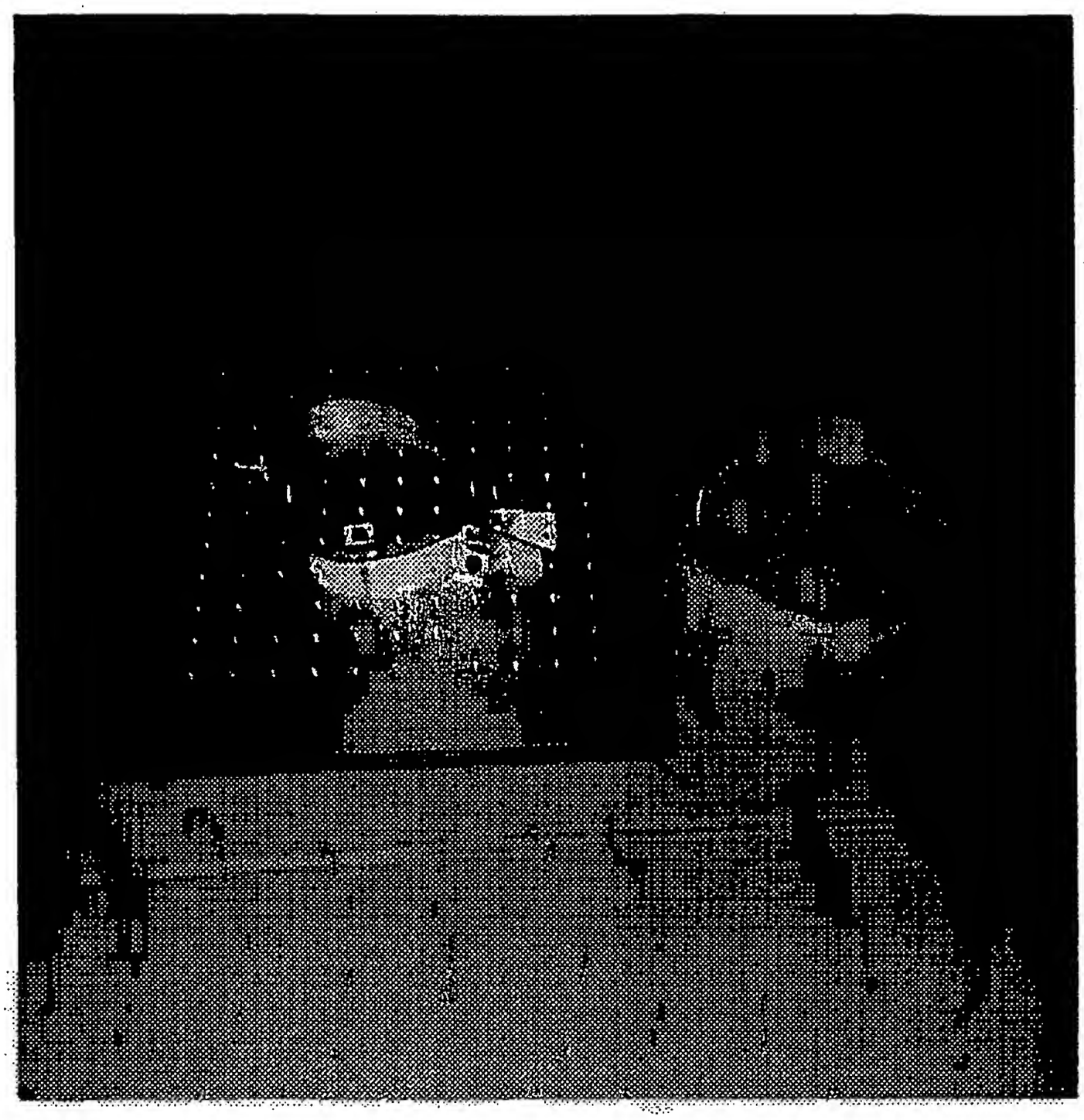

Fig. 9

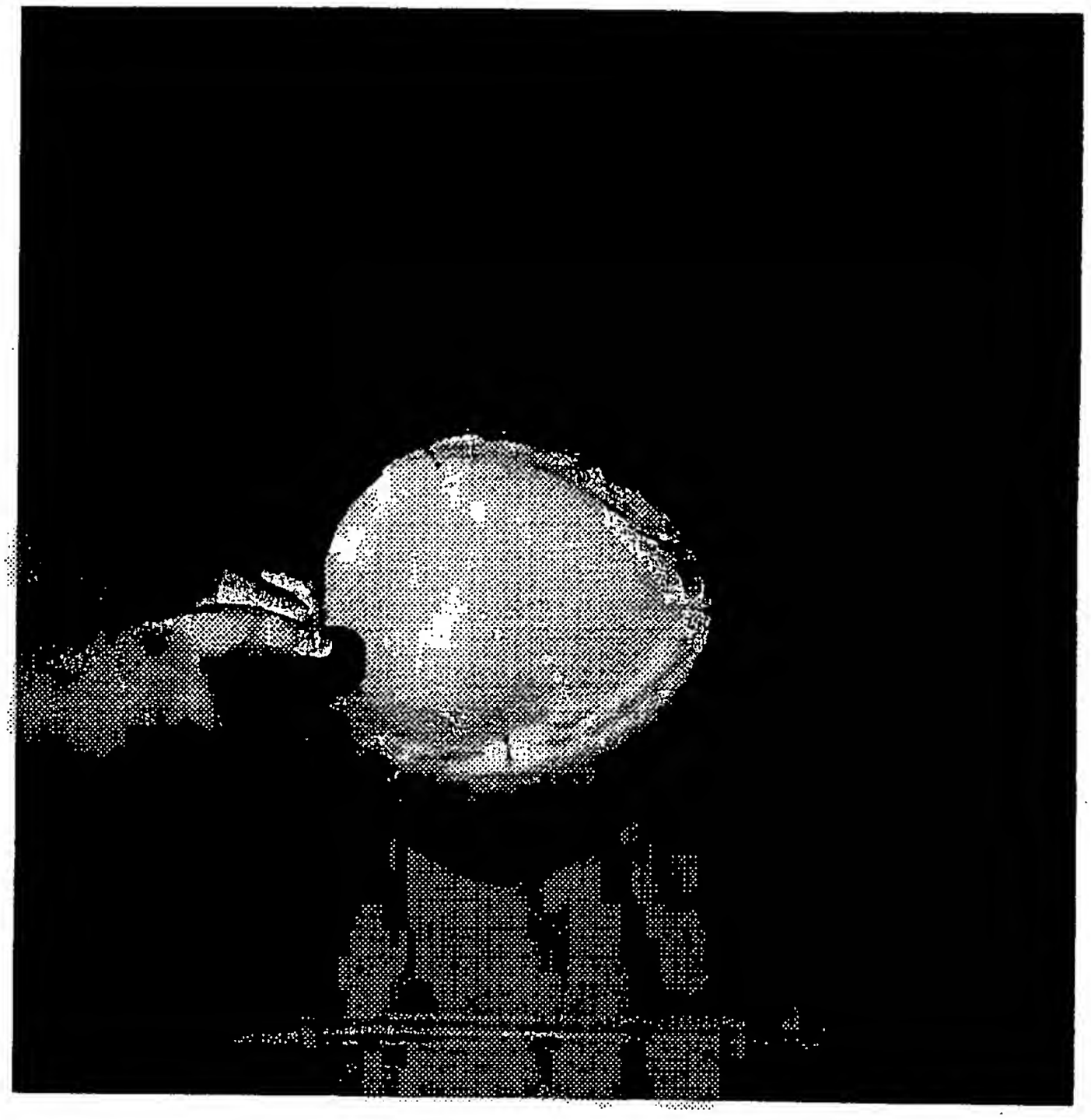

Fig. 10

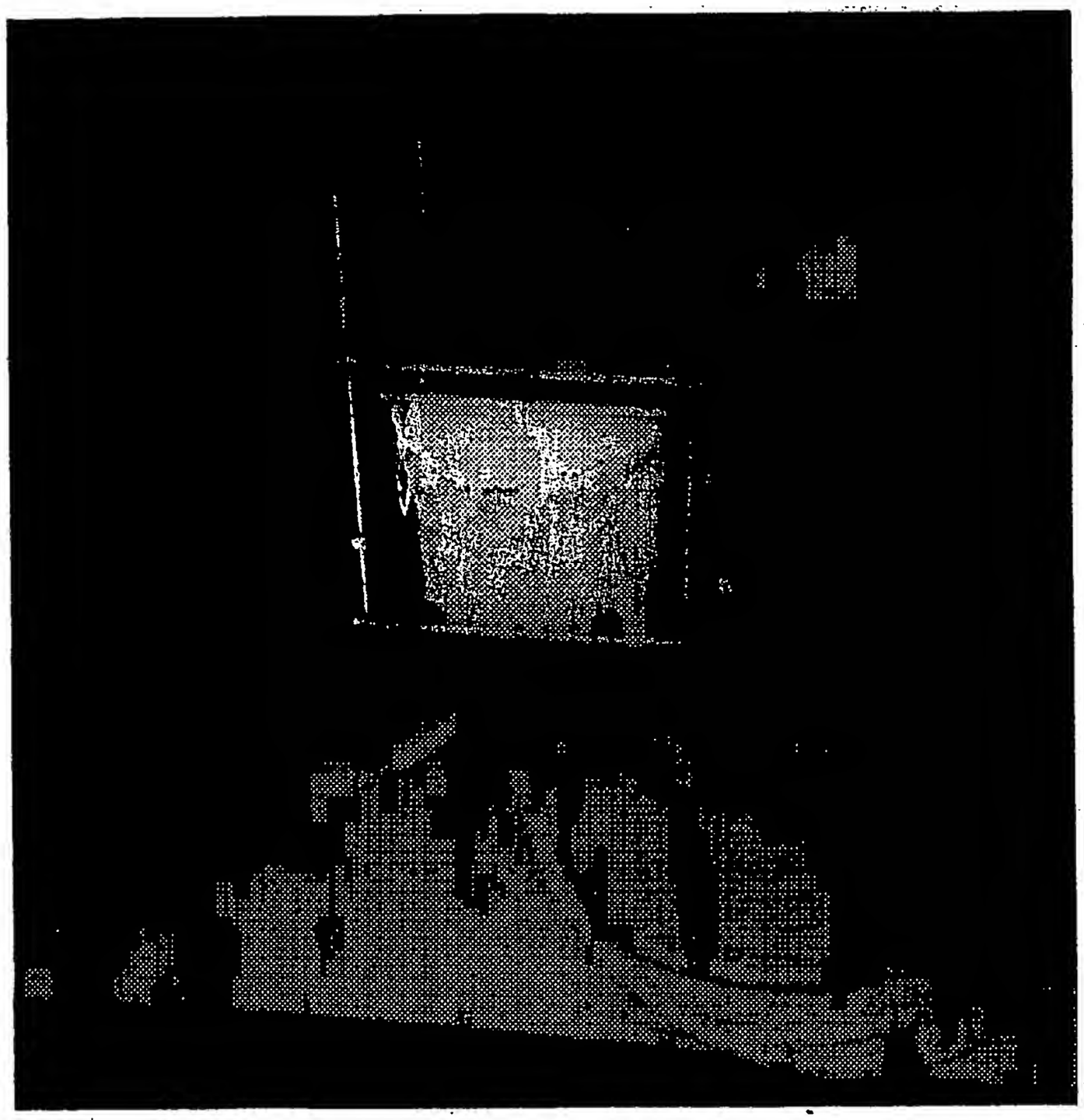

Fig. 11

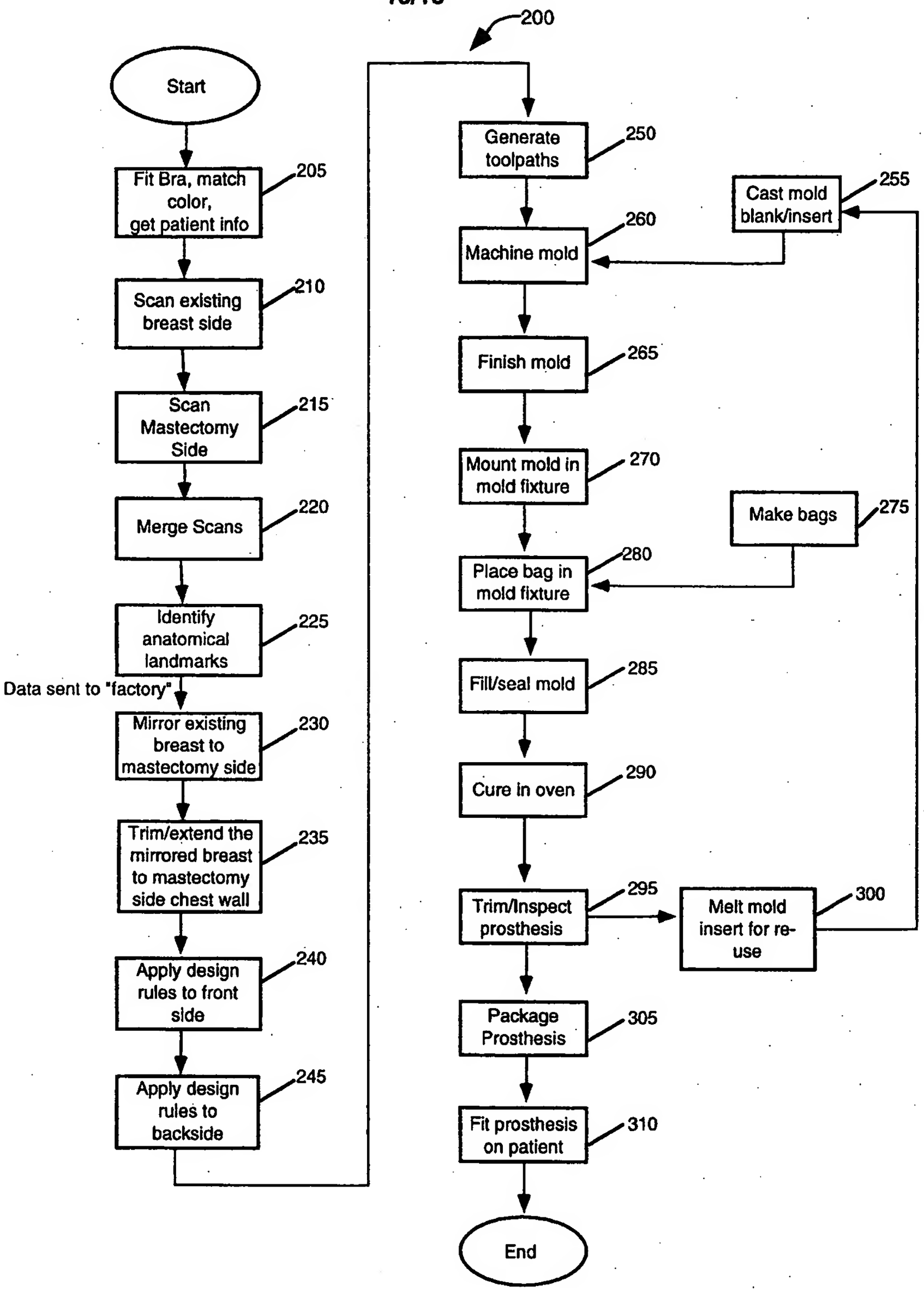
200
Start
Fit Bra, match color, get patient info
205
Scan existing breast side
210
Scan Mastectomy Side
215
Merge Scans
220
Identify anatomical landmarks
225
Data sent to "factory"
Mirror existing breast to mastectomy side
230
Trim/extend the mirrored breast to mastectomy side chest wall
235
Apply design rules to front side
240
Apply design rules to backside
245
Generate toolpaths
250
Machine mold
260
Cast mold blank/insert
255
Finish mold
265
Mount mold in mold fixture
270
Make bags
275
Place bag in mold fixture
280
Fill/seal mold
285
Cure in oven
290
Trim/Inspect prosthesis
295
Melt mold insert for re-use
300
Package Prosthesis
305
Fit prosthesis on patient
310
End

Figure 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/24353

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B29C 45/16; A61F 2/52; G01B 7/04
US CL : 264/40.1; 264/162; 264/222; 623/7

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 264/40.1, 162, 222, 225, 226, 227

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS seatch terms: breast, prosthesis, CAD, mandrel, scan, scanning, CNC, milling

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,575,805 A (MOERMANN et al.) 11 March 1986, see entire document	1-21
Y	US 4,821,200 A (OBERG) 11 April 1989, see entire document	1-21
Y	US 5,432,703 A (CLYNCH et al.) 11 July 1995, see entire document	1-21
Y,P	US 5,798,062 A (THIELBAR) 25 August 1998, see entire document	1-21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance.	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 18 JANUARY 1999	Date of mailing of the international search report 03 FEB 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JAN H. SILBAUGH Telephone No. (703) 308-3829

Form PCT/ISA/210 (second sheet)(July 1992)★